RESEARCH PLAN PROPOSAL

EXPLORATING THE ADHERENCE OF MEDICAL TREATMENT IN VIEW OF THE THEORY OF PLANNED BEHAVIOUR

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Under the supervision of:

Dr. Mridula Sharma
Assistant Professor

Submitted By:

Sarita Gupta
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DEPARTMENT OF PSYCHOLOGY

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Explorating the Adherence of Medical Treatment In View of The Theory of Planned Behaviour

The issue of non-adherence to medical treatment remains a challenge for the medical professions and social scientists. Their efforts to explain and improve a patient's adherence often appear to be ineffective. Although successful adherence interventions do exist, half of interventions seem to fail.

In spite of many advances made in adherence interventions, adherence rates have remained nearly unchanged in the last decades. As a result of this widespread adherence problem, substantial numbers of patients do not get the maximum benefit of medical treatment - with poor health outcomes, lower quality of life and increased health care costs as a result. The impact of poor adherence is felt even more as the burden of patients with chronic diseases grows worldwide. Chronic diseases require long-term adherence.

To that end, this piece of research attempts to understand many of the individual factors, associated with patients' behavior of non-adherence to the treatment advice. To name the few, the individual factors which determine health behavior of the patients are, attitudes towards treatment advice, subjective norms-social influences, and perceived behavioral control of resources.

Adherence

The World Health Organization (WHO) defines adherence as, "the extent to which a person's behavior of taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider." It goes beyond pharmacological therapy and even includes health-related behaviors. When an individual fails to follow the prescribed recommendations of his or her physician in terms of medication and behavioral change, he or she is said to be non-adherent. Non-adherence can not only lead to adverse health outcomes but also increased healthcare costs. Rates of non-adherence are greater in low- and middle-income countries, compared to the developed countries.

An understanding of the factors associated with poor adherence can help the policymakers in formulating and directing interventions at specific groups.

Social / Cognitive Models of Health Behavior

A number of cognitive/social models have been developed to help understand and predict health-related behaviors. These include, for example, the health belief model, the theory of planned behavior, and self-efficacy theory. (Randall E Rogers, 2005) Generally speaking, cognitive theories emphasize the role of mental processes such as reasoning, hypothesizing, and expecting on behavior Specifically, cognitive theorists assert that behavior results from an individual evaluating the worth of a particular outcome and estimating the probability that a particular behavior will result in the outcome.

Health Belief Model

The oldest and most widely researched model is the health belief model. The HBM is a value-expectancy theory that was developed in the 1950's by psychologists working in the Unites States Public Health Service. (Randall E Rogers, 2005) Generally speaking, with regard to health behaviors in particular, "value" translates as the desire to avoid illness or get well, and "expectation" translates as the belief that a particular behavior will prevent illness or improve wellness. The HBM has been widely researched and used to guide the development and evaluation of health behavior related interventions.

The specific components of the HBM include perceived benefits and perceived barriers, which are further delineations of the "value" concept, and perceived susceptibility and perceived severity, which are further delineations of the expectancy concept. Perceived susceptibility refers to a person's estimate of the risk of contracting a particular illness. Perceived severity refers to the individual's estimate of the seriousness of the clinical and social consequences of contracting a particular illness. Taken together, susceptibility and severity create an index of perceived threat.

Self-Determination Theory

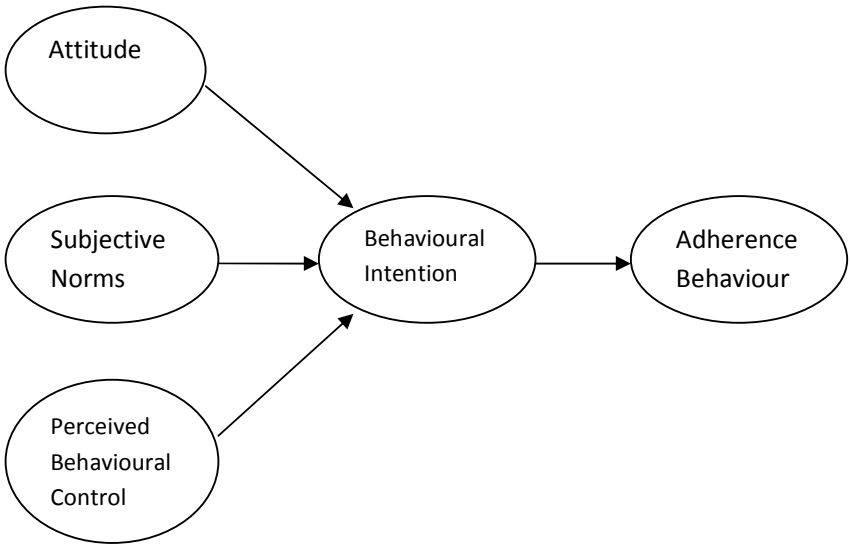
Self-determination theory is a general theory of human motivation that emphasizes the extent to which behaviors are relatively autonomous, i.e., the extent to which behaviors originate from the self, versus relatively controlled, i.e., the extent to which behaviors are pressured or coerced by intra-psychic or interpersonal forces.

It has also offered a particularly comprehensive approach to studying health behavior via its conceptualization and measurement of autonomy, perceived competence, relatedness to others, and its emphasis on the role of the social context in supporting or thwarting optimal motivation.

In the perspective of self-determination theory (SDT: Deci & Ryan, 2000; Ryan & Deci, 2000), recognition of these behavioral mediators of health outcomes suggests that we attend more carefully to the patient's experience and motivation. According to SDT, maintenance of behaviors over time requires that patients internalize values and skills for change and experience self-determination. The theory further argues that by maximizing the patient's experience of autonomy, competence, and relatedness in health-cares settings, the regulation of health-related behaviors is more likely to be internalized, and behavior change will be better maintained (Williams, Deci, & Ryan,1998). As a general theory of motivation, SDT has spawned experimental and field studies of how factors such as rewards, sanctions, use of authority, provision of choice, and level of challenge impact patients' experiences, and in turn their behavioral persistence and outcomes (Deci & Ryan, 2000)

The Theory of Planned Behavior

The theory of planned behavior is one of the most widely applied theoretical models and has been found to be effective in predicting a range of health intentions and behaviors, including dietary behaviors, physical activity, condom use, drug use, and health screening behaviors (Armitage & Conner, 2001; Conner & Sparks, 2005; Hagger & Chatzisarantis, 2009; Hagger et al., 2002; McEachan et al., 2011). It has been beneficial in understanding a range of adherence behaviors including dietary adherence (e.g., Sainsbury & Mullan, 2011), exercise adherence (e.g., Courneya et al., 2008), and medication adherence in a variety of medical conditions.



The theory of planned behavior (TPB) is an extension of the theory of reasoned action (TRA), which asserts that the best predictor of behavior is intention. Intention is in turn determined by attitude toward the behavior and social norms. An important assumption of the TRA, which limits its utility and prompted the development of the TPB, is that the behavior to be predicted is under the individual's volitional control (similar to the HBM).

Subsequently, the authors introduced an additional component, perceived behavioral control, in order to address this issue. If a particular behavior is completely under the person's control, then intentions alone should be adequate at predicting the behavior. However, if the behavior is not completely under the person's control, then perceived behavioral control becomes a more important factor in the prediction. Behavioral control and Bandura's notion of self-efficacy are similar in that they both address beliefs one has about abilities and opportunities to perform a specific action. Perceived behavioral control is comprised of the perceived likelihood of occurrence of a facilitating or inhibiting factor and the perceived power of that factor to facilitate or inhibit the execution of the behavior in question.

Perceived behavioral control influences behavior directly, and indirectly through its influence on intention. Indeed, it could be argued that few behaviors are completely under volitional control, which may be particularly important with regard chronic pain patients, as an increase in pain, lack of endurance, or limited range of motion may prevent them from engaging in

behaviors beneficial to their rehabilitation. Furthermore, the person's perception of the control the have over the behavior is the most important aspect of this component, versus objective control.

As stated earlier, according to the TPB, the best predictor of behavior is intention. Fishbein and Azjen originally defined intention as "the person's subjective probability that he will perform the behavior in question". As specificity of measurement of intention increases, the ability of intention to predict behavior increases. Thus, Fishbein and Azjen suggest that intention be measured with regard to the action to be performed, the time at which it is performed, the context in which it is performed, and the target at which the behavior is directed.

Intention is in part determined by attitude toward the behavior, which is in turn based on the consequences the persons expects will result from the behavior and the benefits and costs, or importance, of those consequences. Intention is also determined by perceived social norms. Perceived social norms is based on normative beliefs, which are estimations of the degree to which others will approve of or support the behavior, and motivation to comply with other's requests. So, in sum, normative beliefs are outcome expectations about other people's attitudes, while motivation to comply is a value expectation referring to the importance the individual places on other's attitudes and expected reactions.

We selected TPB because we expect that the components of this conceptual model reflect important processes that underlie adherence. Specifically, the TPB proposes that people engage in a *behavior* based on their *intention* to perform the behavior, which is a function of a person's *attitude towards the behavior, subjective norms* and *perceived behavioral control.*

REVIEW OF LITERATURE

As adherence to medical advice is a crucial aspect of any treatment procedure, and especially those with chronic illness, it attracts the attention of researchers to look into its dynamics. Many researches have been carried in this regard, a few of studies are stated below:

Rich A. et al. (2015) examined the Theory of Planned Behavior for predicting adherence to treatment in chronic illness across multiple studies. Meta analyses found support for the Theory of Planned Behavior across number of health behavior such as behavior and intention. Reviews also supported the role of intention as a mediator of the effect of attitudes and subjective norms on behavior, and perceived behavioral control as predictor of both intention and behavior. Based on the observation the Theoretical model demonstrates better prediction with shorter time intervals, while adherence in chronic illness, by definition implies a long term prediction. Theoretically consistent patterns of effects among the attitude, subjective norm, perceived behavioral control, intention and behavior constructs were found with small-to-medium effect sizes. Effect sizes were invariant across behavior and measurement type. Although results support theory predictions, effect sizes were small, particularly for the intention-behavior relationship.

Williams G C., et al. (2009) examined the application of Self-determination Theory of health behavior to predict medication adherence, quality of life and physiological outcomes among patients with diabetes. In the study 2973 diabetic patients participated. In this survey the assessment was focussed on the components of SDT, were surveyed assessing perceived autonomy-support from health-care providers, autonomous self-regulation for medication use, perceived competence for diabetes self-management, medication adherence, and quality of life. The outcome of the analysis revealed associations among medication adherence, autonomy support, autonomous self-regulation, and perceived competence in primary care and treatment, thus supporting the SDT model of health behavior.

Balasubramanian A., et al. (2016), examined the Adherence to medication among people with hypertension. The study aimed at assessing the level of adherence to medication and to identify factors associated with it in people with hypertension in a rural population of Kerala. A community-based cross-sectional study was conducted in July 2016 among 189 hypertensives of a rural population in Kerala. Medication adherence was assessed using 4-item Morisky Medication Adherence Scale and Interview method was applied by using semi structured questionnaire to collect the data. It was found in the study that Adherence to medication among people with hypertension in the current study is poor. The risk factors of poor adherence identified were poor knowledge of the complications. The findings lend support for concept of Adherence behavior establishing that poor adherence is an important barrier to adequate blood pressure control among the diagnosed hypertensive.

Von Arx L-BW, et al.(2016) examined Treatment beliefs, health behaviors and their association with treatment outcome in type 2 diabetes. The survey was constructed to operationalize key concepts of diabetes management, diabetes treatment beliefs, and health behaviors and thus study was undertaken to find the extent to which different beliefs and behaviors related to diabetes predict health outcomes. In the large-scale cross sectional study involved people with type 2 diabetes in the county of Funen, Denmark. Health outcome was indicated by glycated haemoglobin (HbA1c) level, blood pressure (BP), total serum cholesterol (s-cholesterol), and low-density lipoprotein (LDL) cholesterol. The health information available from the disease registry was supplemented with self-reported demographic and psychometric data from a questionnaire administered to all insulin-treated people in the registry (n=3160). Perceived low treatment efficacy was the only health belief associated with poorer levels of health outcome other than HbA1c. It was found that Health behaviors were stronger predictors for health outcomes than treatment beliefs. Self-reported adherence to either the treatment regimen or general medical advice most consistently predicted both glycemic control and cardiovascular risk factors

DiMatteo M. R. et. al. (2002) in their comprehensive study have searched 116 articles with 143 researches (published literature between 1948- 2005), summarized with meta analysis of r effect sizes and moderators of the relationship between patient adherence and patients': (1) beliefs in disease threat; (2) rated health status (by physician, self, or parent); and (3) objective disease severity. The results showed that adherence is significantly positively correlated with patients' beliefs in the severity of the disease to be prevented or treated ("disease threat"). Better patient adherence is associated with objectively poorer health only for patients experiencing disease conditions lower in seriousness (according to the Seriousness of Illness Rating Scale). Among conditions higher in seriousness, worse adherence is associated with objectively poorer health. Thus, the results suggest that the objective severity of patients' disease conditions, and their awareness of this severity, can predict their adherence. Patients who are most severely ill with serious diseases may be at greatest risk for nonadherence to treatment. Findings contribute to greater provider awareness of the potential for patient non-adherence, and to better targeting of health messages.

Jones D., et al. (2012), examined the impact of an immediate- versus delayed-onset intervention to evaluate the impact of establishing adherence behaviors early on in the use of ARV medications. This pilot study sought to evaluate the barriers and facilitators associated with adherence and the impact of a group-based intervention designed to enhance adherence in comparison with an individual enhanced standard of care. The intervention utilized information and social support to motivate patient–provider communication and treatment adherence and enhance positive beliefs and behaviors related to ARV medication.

Thus, evaluated an intervention designed to enhance adherence among those new to antiretroviral therapy with the focus on Enhancing HIV medication adherence in India. The participants (n=80) were subjected to a 3-month group intervention or individual enhanced standard of care followed by crossover of condition and assessed over 6 months. Adherence was measured by prescription refill, pill count, and self-report. Results support the use of interventions early in treatment to provide information and social support to establish long-term healthy adherence behaviors. Finally, it was emphasized that apart form the need for targeted interventions for non-adhering patients, maintaining long-term adherence may require an early intervention strategy, making communication and problem-solving strategies a key component for successful adherence to “lifelong” medication.

Luga A. O., et al. (2014) examined the most recent developments in adherence research with a focus on the impact of medication adherence on health care costs in the US health system. This review provides a general overview of non-adherence, its cost in specific illnesses, and approaches to improving medication adherence. It has been described in the review the the magnitude of the non-adherence problem and related costs, also discussed extensively, the mechanisms underlying the impact of non-adherence on costs. Specifically, summarizing the impact of non-adherence on health care costs in several chronic diseases, such as diabetes and asthma. The analyses of relationship between nonadherence and associated health care cost revealed that medication nonadherence leads to poor outcomes, which then increase health care service utilization and overall health care costs. The study pointed out that improved adherence can be achieved through better education, value-based insurance designs, and thoughtful use of patient incentives. Ultimately collaboration between patients, payers, policy makers and providers, and redesigning systems to employ more team-based care, use lower cost medications, and target highest cost illnesses, will be needed to achieve better adherence and optimize spending.

Kim H.S., et.al.(2012) investigated how university students' nutrition beliefs influence their health behavioral intention. Using the Health Belief Model, this study attempts (a) to investigate college students' health behavior, (b) to address the determinants of eating behavior and physical activity and (c) to assess if those underlying factors are interrelated. The insight into how and why health behaviors are developed is important to the success and adaptability of promoting healthy lifestyles to college students. This study used an online survey engine to collect data from college students and used 251 questionnaires for the statistical analysis. The results validate that objective nutrition knowledge was a good predictor of college students' nutrition confidence. The results also clearly showed that two direct measures were significant predictors of behavioral intentions. Perceived benefit of eating healthy food and perceived barrier for eat healthy food to had significant effects on Behavioral Intentions and was validated by the result of the analysis. These findings can find its application within other health care or foodservice settings and for other health behavioral categories.

Jannuzzi F F., et.al. (2014) studied salient behavioural, normative, control and self-efficacy beliefs related to the behaviour of adherence to oral antidiabetic agents, using the Theory of Planned Behaviour. In The sample was composed of 17 individuals, most of whom were women (64.7%), aged 59.8 years old on average. In the analysis. behavioural beliefs concerning advantages and disadvantages of adhering to medication emerged, such as the possibility of avoiding complications from diabetes, preventing or delaying the use of insulin, and a perception of side effects. The children of patients and physicians are seen as important social references who influence medication adherence. The factors that facilitate adherence include access to free-of-cost medication and taking medications associated with temporal markers. On the other hand, a complex therapeutic regimen was considered a factor that hinders adherence. Understanding how to use medication and forgetfulness impact the perception of patients regarding their ability to adhere to oral antidiabetic agents. Investigation concerning the influence of beliefs in regard to the intention to adhere to oral antidiabetic agents can support interventions focused on the promotion of medication adherence among DM patients.

Chisholm M. A. et.al. (2006) applied Theory of Planned Behaviour (TPB) variables (attitudes, subjective norms and perceived behavioural control) relevant to intentions to adhere to their IST, with the addition of a general measure of past adherence to medical advice. The sample of 164 RTPs, who were enrolled in the Medication Access Program (MAP). MAP is a statewide program that provides medication access to solid-organ transplant recipients who reside in the State of Georgia. The objective of this study was to increase the ability to predict renal transplant patients (RTPs) who are most likely to be non-adherent to their immunosuppressant therapy (IST). . One hundred and fifty-eight RTPs completed questionnaires. The results provided strong support for the TPB, however there was no evidence for an effect of subjective norms. Results of this study were consistent with the TPB framework and provided insight into the factors underlying medication adherence. The results provide insights about ways to forestall or possibly avoid non-adherence, which may find its application in clinical setting.

METHODOLOGY

RATIONALE

The problem of non-adherence to medical treatment remains a challenge for the medical professions and social scientists. In spite of many advances made in adherence interventions, adherence rates have remained nearly unchanged in the last decades. As a result of this widespread adherence problem, substantial numbers of patients do not get the maximum benefit of medical treatment - with poor health outcomes, lower quality of life and increased health care costs as a result. The impact of poor adherence is felt even more as the burden of patients with chronic diseases grows worldwide.

Non-adherence can result in significant mortality, long term disability and financial cost. Very few studies have been conducted on adherence to treatment advice by the patients, in Indian context. In the present research an attempt has been made to understand the predictors of non-adherence using the framework of Planned Behavior Theory via looking into the constructs as subjective norms, attitude towards adherence and perceived behavioral control.

Objectives

- To study the relationship between subjective norms and adherence to the medical treatment.
- To study the relationship between attitude towards behavior and adherence to the medical treatment.
- To study the relationship between perceived behavioral control and adherence to the medical treatment.
- To study the mediation of Behavioral Intent on relationship between subjective norms and adherence to the medical treatment.
- To study the mediation of Behavioral Intent on relationship between attitude and adherence to the medical treatment.
- To study the mediation of Behavioral Intent on relationship between perceived behavioral control and adherence to medical treatment.

- To study relationship of attitude, subjective norms and perceived behavioral control with behavioral intent.
- To study relationship of attitude, subjective norms and perceived behavioral control with adherence behaviour.

Hypotheses:

- There will be significant relationship between Subjective Norms and Adherence Behaviour.
- There will be significant relationship between Attitude and Adherence Behaviour.
- There will be significant relationship between Perceived Behavioral Control and Adherence Behaviour.
- Behavioral Intent will significantly mediate the relationship between subjective norms and adherence Behaviour.
- Behavioral Intent will significantly mediate the relationship between Attitude and Adherence Behaviour.
- Behavioral Intent will significantly mediate the relationship between Perceived Behavioral Control and Adherence Behaviour.
- There will be significant relationship among attitude, subjective norms and perceived behavioral control with Behaviour intent.
- There will be significant relationship among attitude, subjective norms and perceived behavioral control with Adherence behaviour.

Sample

The total sample for the present study will comprise 300 adults (both male and female) between the age of 40-60 years, having physiological Chronic diseases (Type 2 diabetes and Hypertension), from upper middle socio-economic background. In present study purposive sampling technique will be used to select the sample.

Criteria of inclusion

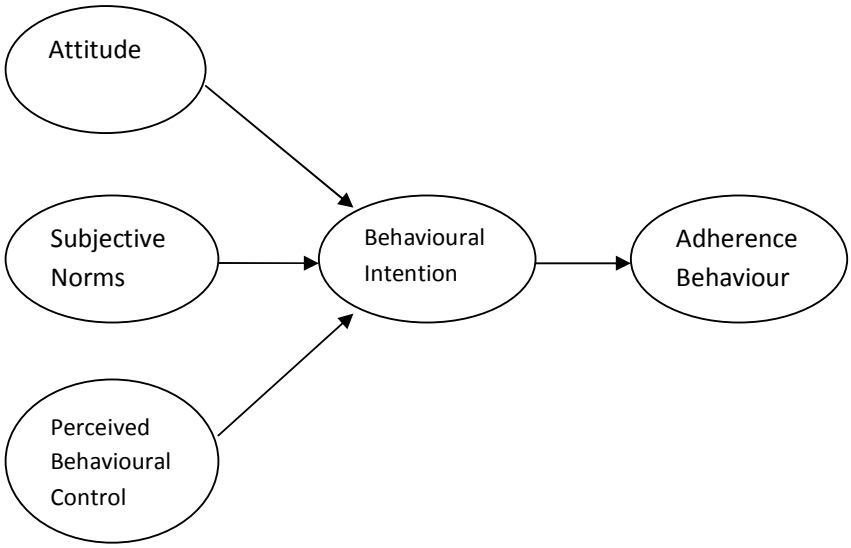
- Socio-economic status: Upper Middle class
- Age: Within the age group of 40-60 years

Criteria of exclusion

- People with any kind of psychiatric history.
- People not fulfilling the inclusion criteria.
- People who have undergone surgery as a consequence of chronic disease

RESEARCH DESIGN

The present research is a causal research.



MEASURES:

- **Self reporting scale for measuring adherence to medication/MARS**

The Medication Adherence Rating Scale (MARS) was developed from Morisky et al's Medication Adherence Questionnaire (MAQ) is a ten-item self-report measure of medication adherence in psychosis (Table Below). To summarise, the MARS is a quick, non-intrusive measure of medication adherence. It's reliability is adequate, but validity appears to only moderate – weak. Items in the MARS about attitude to medication may be informative to clinicians identifying barriers to adherence in individual cases, but do not appear to be valuable in predicting adherence behavior over a large sample. Factor 1 (medication adherence behavior), corresponding to the MAQ, may be superior for this purpose. The internal consistence of the MARS was (alpha=0.60)

- **Behaviour Intentions Questionnaire**

- **Theory of Planned Behaviour Questionnaire (TPB Questionnaire)**

According to the theory, human behaviour is guided by three kinds of considerations: beliefs about the likely consequences of the behaviour (Behavioural beliefs), beliefs about the normative expectations of others (normative beliefs), and beliefs about the presence of factors that may facilitate or impede performance of the behaviour (control beliefs). In their respective aggregates, behavioural beliefs produce a favourable or unfavourable attitude toward the behaviour; normative beliefs result in perceived social pressure or subjective norm; and control beliefs give rise to perceived behavioural control. In combination, attitude towards the behaviour, subjective norm, and perception of behavioural control lead to the formation of behavioural intent.

The theory's major constructs: Attitude, Perceived Norm, Perceived behavioural control, and intention. Seven-point bipolar adjective scales are typically employed. Participants are asked to circle the number that best describes their personal opinions. Care has been taken that the items are formulated to be exactly compatible with the behavioural criterion and to be self-directed.

STATISTICAL ANALYSIS

- Descriptive statistical measures
- Correlation
- Regression
- Meditational Analysis By SPSS

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Appendix 1

The Medication Adherence Rating Scale (MARS)

Number	Claim or Questions	Compliance	
		Yes	No
1.	Do you ever forget to take your medication?		
2.	Are you careless at times at taking medication?		
3.	When you feel better, do you sometimes stop taking your medication?		
4.	Sometimes, if you feel worse when you take medication, do you stop taking it?		
5.	I only take my medication, when I am sick.		
6.	It is unnatural for my mind and body to be controlled by medication.		
7.	My thoughts are clearer on medication.		
8.	By staying on medication, I can prevent getting sick.		
9.	I feel weird, like a zombie, on medication.		
10.	The medication makes me feel tired and sluggish		

Appendix 2

Behavioural Intentions Questionnaire

Below is a list of five behaviours. Circle the response that best reflects your intention to perform the behaviour on a daily basis.

Behaviour 1: Get up at about the same time every day (within an hour or so) – even on weekends.

I don't plan to I want to I need to I will I already do I tried to

Behaviour 2: Spend at least half an hour outside soon after waking up every day even on weekends.

I don't plan to I want to I need to I will I already do I tried to

Behaviour 3: Drink less caffeinated drinks in the afternoon and evening (coffee, tea, cola, energy drink viz. red bull).

I don't plan to I want to I need to I will I already do I tried to

Behaviour 4: Increase average night's sleep over a whole week to between 8.5 and 9.5 hours.

I don't plan to I want to I need to I will I already do I tried to

Behaviour 5: Avoid "sleeping in" on weekendsmore than 2 hours past my normal school□day wake□up time.

I don't plan to I want to I need to I will I already do I tried to

Thank you for completing this questionnaire.

Please make sure that you hand it to your teacher at the end of class.

© Cain, Moseley, & Gradisar (2009)

Appendix 3

Theory of Planned Behaviour Questionnaire (TPB Questionnaire)

This questionnaire includes the following elements.

Behavioral Beliefs and Outcome Evaluations

With respect to each salient behavioral outcome, items are formulated to assess the strength of the behavioral beliefs and the evaluation of the outcome.

Sample Outcome: faster recovery from my chronic illness (B.P. / Diabetes)

Behavioral belief strength

My exercising for at least 20 minutes, three times per week for the next 3 months will result in my having a faster recovery from my illness.

Likely	1	2	3	4	5	6	7	Unlikely

Outcome evaluation

My having a faster recovery from my illness is

Good	1	2	3	4	5	6	7	Bad

(2a) Injunctive Normative Beliefs and Motivation to comply

With respect to each salient normative referent, items are formulated to assess the strength of the injunctive normative belief and the motivation to comply with the referent individual.

Injunctive Normative Referent: My Doctor

Injunctive Normative Belief strength

My doctor thinks that

I should	1	2	3	4	5	6	7	I should not

exercise for at least 20 minutes, three times per week for the next 3 months.

Motivation to comply

When it comes to matters of health, I want to do what my doctor thinks I should do.

Agree	1	2	3	4	5	6	7	Disagree

(2b) Descriptive Normative Beliefs and Identification with the Referent

With respect to each relevant salient referent, items are formulated to assess the strength of the descriptive normative belief and the identification with the referent individual.

Descriptive Normative Referent: My friends / relations

Descriptive Normative Belief strength

Most of my friends / relatives who were suffering from chronic illness (B.P. / Diabetes) have exercised for at least 20 minutes, three times per week for the next 3 months.

False	1	2	3	4	5	6	7	True

Identification with the referent

When it comes to matters of health, how much do you want to be like your friends / relatives.

Very Much	1	2	3	4	5	6	7	Not at all

(3) Control Beliefs and Power of Control Factors

With respect to each salient control factor, items are formulated to assess the likelihood that the factor will be present and the factor's power to facilitate or impede performance of the behavior.

Control Factor: Physical strength

Control belief strength

I expect that I will have physical strength in the next 3 months.

Likely	1	2	3	4	5	6	7	Unlikely

Power of control factor

Having physical strength would enable me to exercise for at least 20 minutes, three times per week for the next 3 months.

Disagree	1	2	3	4	5	6	7	Agree